



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,838	12/22/2005	Hideki Kubota	281748US0PCT	2991
22850	7590	04/02/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			04/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/561,838	Applicant(s) KUBOTA ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-17 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-17 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/06, 7/06, 3/07, 8/07</u> . | 6) <input type="checkbox"/> Other: _____ |

The Status of Claims :

Claims 1-5,7-17, 21-23 are pending.

Claims 1-5,7-17, 23 are rejected.

Claims 21-22 are withdrawn from consideration.

DETAILED ACTION

1. Claims 1-5,7-17, 23 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/JP04/09132 (06/29/2004), which has a foreign documents: Japan 2003-187796(06/30/03) and Japan 2004-099151(06/30/03).

Drawings

3. None.

The Restriction Requirement sent on 11/17/2008 is replaced by the following new the Lack of Unity.

The Lack of Unity

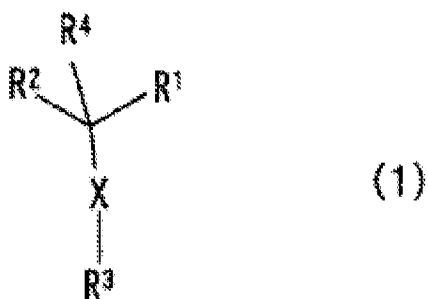
Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

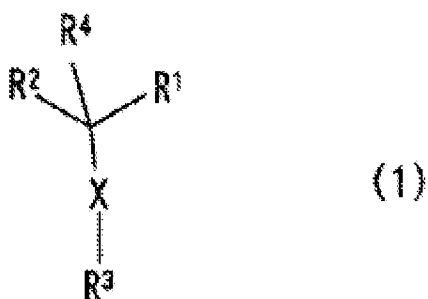
Group I, claims 1-5,7-17, 23 is drawn to the following compound formula (I)

containing all R1 and R2 and R3 which are a pyridyl moiety and its pharmaceutical composition as disclosed below :



Group II, claims 1-5,7-17, 23 is drawn to the following compound formula (I)

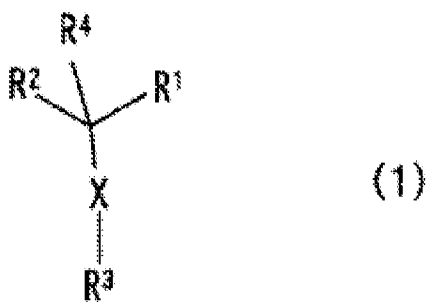
containing all R1 and R2 and R3 which are a thienyl moiety and its pharmaceutical composition as disclosed below :



Art Unit: 1625

Group III, claims 1-5,7-17, 23 is drawn to the following compound formula (I)

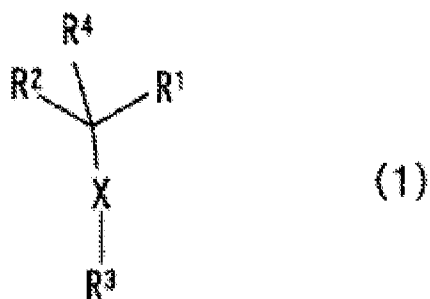
containing all R1 and R2 and R3 which are a non-heteroaryl, non-heterocyclic or phenyl moiety and its pharmaceutical composition as disclosed below :



Group IV, claims 1-5,7-17, 23 is drawn to the following compound formula (I)

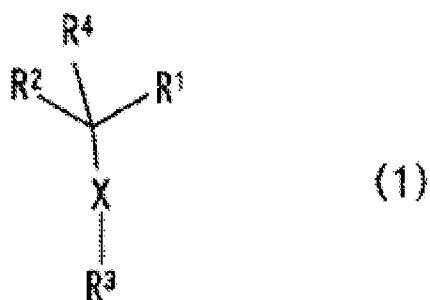
containing other types of aromatic heteroaryl, monocyclic heterocyclic compounds, i.e. pyrrolidinyl, imidazolyl, isoxazoly, thiazolyl,thiomorpholinyl, furanyl, , thiranyl, tetrahydropyranyl, benzopyranyl, dioxolanyl, piperazinyl, morphole, isothiazolidinyl, thiophenyl and its pharmaceutical composition as disclosed below :

Art Unit: 1625



Group V, claims 21-22, is drawn to the method for treating a disease resulting from abnormal production or secretion of beta-amyloid protein or Alzheimer disease by using the compound formula (I).

Group VI, claims 1-5, 7-17, 23 is drawn to the following compound formula (I) where R¹ is a phenyl group and R² and R³ are each a pyridyl group and its pharmaceutical composition as disclosed below:



A. The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“ requirement of unity of invention ”).

PCT Rule 13.2 states “ Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “ special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety , and its pharmaceutical composition, whereas the invention II is related to the compound formula (I) containing all R^1 and R^2 and R^3 which are a thienyl moiety and its pharmaceutical composition. They have different modes of operation , different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

Art Unit: 1625

Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention III is related to the compound formula (I) containing all R^1 and R^2 and R^3 which are a non-heteroaryl, non-heterocyclic or phenyl moiety and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention IV is related to the compound formula (I) containing all various R^1 and R^2 and R^3 which are pyrrolidinyl, imidazolyl, isoxazolyl, thiazolyl, thiomorpholinyl, furanyl, thiranyl, tetrahydropyranyl, benzopyranyl, dioxolanyl, piperazinyl, morphole, isothiazolidinyl, thiophenyl and its pharmaceutical composition. They have different modes of operation, different functions or

Art Unit: 1625

different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety and its pharmaceutical composition, whereas the invention V is related to the method for treating a disease resulting from abnormal production or secretion of beta-amyloid protein or Alzheimer disease by using the compound formula (I). The prior art Fasman (US 5,523,295) discloses the followings:

A method for treating or preventing Alzheimer's disease in a mammal is described. A silicon compound for inhibiting interaction between aluminum and β -amyloid or neurofilament protein is provided. The silicon compound is administered to a mammal in need of such treatment to cause this inhibition to occur.

This compound is structurally unrelated to the claimed compounds of formula (I). Therefore, there is no special technical feature of Group I required in Group V. There is no single general

Art Unit: 1625

inventive concept and no unity of invention for the method or the processes as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention VI is related to the compound formula (I) containing R^1 is a phenyl group and R^2 and R^3 are each a pyridyl group and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group VI are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

Applicant's election with traverse of Group VI (claims 1-5,7-17, 23) on 1/21/09 is acknowledged.

Claims 1-5,7-17, 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups I-V, there being no allowable generic or linking claims.

Applicants argue the following issue:

1. The Office did not consider the contribution of the invention as a whole in alleging a lack of Unity of Invention in view of the determination which is to be the contents of the claims as interpreted in light of description; therefore, the Office has not met the burden for establishing the alleged lack of Unity of Invention.

With respect to applicants' arguments, the examiner has noted applicants' arguments.

However, unlike applicants' argument, each of Groups I-VI lacks a special technical feature among them because there are many different inventions present in the application as a whole in spite of the alleged unity of the invention being present in the application.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention II is related to the compound formula (I) containing all R^1 and R^2 and R^3 which are a thienyl moiety and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

Art Unit: 1625

Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention III is related to the compound formula (I) containing all R^1 and R^2 and R^3 which are a non-heteroaryl, non-heterocyclic or phenyl moiety and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention IV is related to the compound formula (I) containing all various R^1 and R^2 and R^3 which are pyrrolidinyl, imidazolyl, isoxazolyl, thiazolyl, thiomorpholinyl, furanyl, thiranyl, tetrahydropyranyl, benzopyranyl, dioxolanyl, piperazinyl, morphole, isothiazolidinyl, thiophenyl and its pharmaceutical composition. They have different modes of operation, different functions or

Art Unit: 1625

different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group II are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety and its pharmaceutical composition, whereas the invention V is related to the method for treating a disease resulting from abnormal production or secretion of beta-amyloid protein or Alzheimer disease by using the compound formula (I). The prior art Fasman (US 5,523,295) discloses the followings:

A method for treating or preventing Alzheimer's disease in a mammal is described. A silicon compound for inhibiting interaction between aluminum and β -amyloid or neurofilament protein is provided. The silicon compound is administered to a mammal in need of such treatment to cause this inhibition to occur.

This compound is structurally unrelated to the claimed compounds of formula (I). Therefore, there is no special technical feature of Group I required in Group V. There is no single general inventive concept and no unity of invention for the method or the processes as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the compound formula (I) containing all R^1 and R^2 and R^3 which are a pyridyl moiety, and its pharmaceutical composition, whereas the invention VI is related to the compound formula (I) containing R^1 is a phenyl group and R^2 and R^3 are each a pyridyl group and its pharmaceutical composition. They have different modes of operation, different functions or different effects because each of their reactants has a completely different chemical structure with respect to the core structure. For example, the reactant containing a hetero group has been known to have a different reactivity or a different effect in comparison with the one with the non-hetero groups. Therefore, Group I and Group VI are unrelated to each other. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds. Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

As indicated in the above, the two or more separate Groups I-VI can pose undue a great deal of burden on the Examiner because each group may possess many variations or permutations of the claimed compounds and compositions; therefore, each requires conducting a new search due to being totally different fields of inventions among them.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5,7-17, 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. “The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples,

Art Unit: 1625

the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, “it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent”. Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of

formula (1) as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrases " an aromatic hydrocarbon group --- an aromatic heterocyclic group " and " monocyclic heterocyclic group --- polycyclic heterocyclic group" are recited. Each expression of the phrases: aromatic hydrocarbon group , an aromatic heterocyclic group " , monocyclic heterocyclic group , polycyclic heterocyclic group is vague and indefinite because the claim does not elaborate what is meant by each term ; there is no definitive carbon atom range for the hydrocarbon and there are no specific heteroatoms for the heterocyclic group.

Furthermore, the term “hydrocarbon” may mean that a compound consisting of carbon and hydrogen, but there are numerous hydrocarbons known in the organic chemistry ; there is uncertainty as to what kind of “hydrocarbon” can be applied for the process. Therefore, an appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

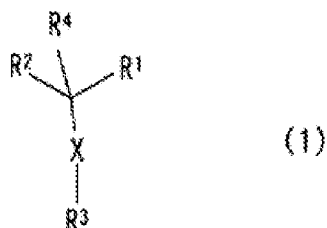
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,7-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-28 of copending Application No. 11/829,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention differs from the copending Application No. 11/829,533.

Claim 1 of the instant invention describes as below :

Claim 1 (Currently Amended): A compound represented by the following formula (1):

~~[Chemical formula 1]~~



~~(wherein; wherein,~~

R¹ and R³ each independently represents an aromatic hydrocarbon group which may have a substituent or an aromatic heterocyclic group which may have a substituent,

R² represents a saturated or unsaturated monocyclic heterocyclic group or unsaturated polycyclic heterocyclic group which may have a substituent,

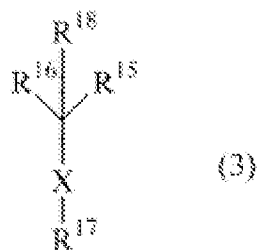
R⁴ represents a hydrogen atom or a C₁₋₆ alkyl group,

X represents -S-, -SO- or -SO₂- -SO₂-);

an N-oxide or S-oxide thereof; a salt thereof; or a solvate thereof.

Whereas the claim 18 of application 11/829,533 describes as below :

18. (New) A compound represented by the following formula (3):



Art Unit: 1625

wherein

R^{15} represents a heterocyclic group which may have a substituent,

R^{16} represents a cyclic hydrocarbon group which may have a substituent or a heterocyclic group which may have a substituent,

R^{17} represents pyridyl group which may have at least one substituent,

R^{18} represents a hydrogen atom or a C_{1-6} alkyl group, and

X represents -S-, -SO- or -SO₂;

or N-oxide or S-oxide of the compound; salt thereof; or solvate of the above-described compound.

However, the instant invention differs from the copending application in that the variable R3 of the claimed invention shows a broad range of compounds in comparison with R17 being a pyridyl group of the copending application.

Even so, they are related to each other as the genus-species relationship. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to limit the scope of the invention in order to emphasize the particular aspect of the species of the claimed invention as an alternative. This is because the skilled artisan in the art would expect such a modification to be successful and manageable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

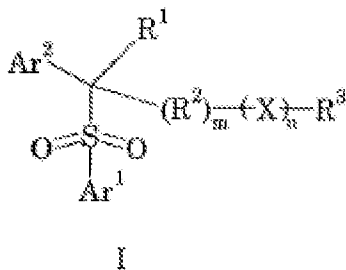
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5,7-17 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Harrison et al (WO 02/081433).

Harrison et al discloses the following compounds of formula (I) as shown below (see page 3, lines 1-25 and page 4, lines 1-19) :

The present invention provides a pharmaceutical composition comprising, in a pharmaceutically acceptable carrier, a compound of formula I:



wherein:

Ar¹ represents C₆₋₁₀aryl or heteroaryl, either of which bears 0-3 substituents independently selected from halogen, CN, NO₂, CF₃, OH, C₁₋₄alkoxy or C₁₋₄alkyl which optionally bears a substituent selected from halogen, CN, NO₂, CF₃, OH and C₁₋₄alkoxy;

Ar² represents C₆₋₁₀aryl or heteroaryl, either of which bears 0-3 substituents independently selected from halogen, CN, NO₂, CF₃, OH, C₁₋₄alkoxy or C₁₋₄alkyl which optionally bears a substituent selected from halogen, CN, NO₂, CF₃, OH and C₁₋₄alkoxy;

R¹ represents H, or C₁₋₆alkyl, C₃₋₆cycloalkyl or C₂₋₆alkenyl, any of which is optionally substituted by halogen, CN, NO₂, CF₃, OH, C₁₋₄alkoxy or C₁₋₄alkoxycarbonyl;

R² represents a saturated or unsaturated hydrocarbon linking group of up to 6 carbon atoms;

X represents -O-, -S-, -SO₂-, -N(R⁴)-, -C(O)-, -OC(O)-, -C(O)O-, -C(O)N(R⁴)-, -N(R⁴)C(O)-, -OC(O)O-, -N(R⁴)C(O)O-, -OC(O)N(R⁴)-, -SO₂N(R⁴)- or -N(R⁴)SO₂-;

R³ represents C₁₋₁₀alkyl, C₃₋₆cycloalkyl, C₃₋₆cycloalkylC₁₋₄alkyl, C₂₋₆alkenyl or C₂₋₆alkynyl, any of which may be substituted by halogen, CN, NO₂, CF₃, Ar, heterocyclyl, OR⁴, N(R⁴)₂, COR⁴, CO₂R⁴, OCOR⁴, or CON(R⁴)₂; or R³ represents Ar or heterocyclyl;

Art Unit: 1625

R⁴ represents H, C₁₋₄alkyl or Ar, or two R⁴ groups together with a nitrogen atom to which they are mutually attached may complete an N-heterocyclyl group;

Ar represents phenyl or heteroaryl bearing 0-3 substituents selected from halogen, C₁₋₄alkyl, CN, NO₂, CF₃, OH, C₁₋₄alkoxy, C₁₋₄alkoxycarbonyl, amino, C₁₋₄alkylamino, di(C₁₋₄alkyl)amino, carbamoyl, C₁₋₄alkylcarbamoyl and di(C₁₋₄alkyl)carbamoyl;

m and n are each 0 or 1, provided that m = 0 if n = 0;

"heterocyclyl" at every occurrence thereof means a cyclic or polycyclic system of up to 10 ring atoms selected from C, N, O and S, wherein none of the constituent rings is aromatic and wherein at least one ring atom is other than C, bearing 0-3 substituents selected from =O, =S, halogen, C₁₋₄alkyl, CN, NO₂, CF₃, OH, C₁₋₄alkoxy, C₁₋₄alkoxycarbonyl, amino, C₁₋₄alkylamino, di(C₁₋₄alkyl)amino, carbamoyl, Ar and COAr; and

"heteroaryl" at every occurrence thereof means a cyclic or polycyclic system of up to 10 ring atoms selected from C, N, O and S, wherein at least one of the constituent rings is aromatic and wherein at least one ring atom of said aromatic ring is other than C;

or a pharmaceutically acceptable salt thereof.

The expression "heteroaryl" as used herein means a cyclic or polycyclic system of up to 10 ring atoms selected from C, N, O and S, wherein at least one of the constituent rings is aromatic and wherein at least one ring atom is other than carbon. Preferably not more than 3 ring atoms are other than carbon. Where a heteroaryl ring comprises two or more atoms which are not carbon, not more than one of said atoms may be other than nitrogen. Examples of heteroaryl groups include pyridinyl,

(see page 5

,lines 25-31).

This is identical with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh, MSD,LAC
Primary Examiner
Art Unit: 1625

/Taylor Victor Oh/

Primary Examiner, Art Unit 1625

3/25/09